UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
	Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO: ALL CLASS ACTIONS	Judge Patti B. Saris

TRACK 1 DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR MOTION TO PRECLUDE THE EXPERT TESTIMONY OF DR. RAYMOND HARTMAN IN CONNECTION WITH CLASS 3

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

The Track 1 Defendants respectfully submit this memorandum in support of their motion to preclude the expert testimony of Dr. Raymond Hartman ("Hartman") with respect to Class 3 pursuant to *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993).

Preliminary Statement

In our brief on Classes 1 and 2, we explained why Hartman's expectation theory— that the marketplace expected AWP to exceed ASP by no more than 30% — does not satisfy minimum *Daubert* standards. Among other things, we explained that (1) the premise on which it is based (that payors have expected that AWP is larger than ASP by a reasonably predictable amount) is demonstrably incorrect; (2) Hartman's 30% yardstick ignores, and is inconsistent with, evidence of actual expectations; and (3) the surrogates he employs for determining expectations— comparator drugs, publicly available reports and his theory of "revealed preferences"— do not support his expectation yardstick.[1] Hartman's expectation yardstick is nothing more than an unsupported assertion.[2]

While plaintiffs have stipulated that they do not intend to call Hartman to testify about his expectation theory in any trial involving claims by Classes 1 and 2,[3] there can be no doubt that his theory applies to the Class 3 claims. His report explicitly says so.[4] As the Court observed in its opinion on class certification, Hartman "intends to determine what the market

[1] *See* Track 1 Defendants' Memorandum in Support of Their Motion to Preclude the Expect Testimony of Dr. Raymond Hartman in Connection With Classes 1 and 2 ("Class 1 and 2 Mem."), at 10-22. That brief is incorporated by reference as if fully set forth herein. In addition, the declarations supporting the *Daubert* motion for Classes 1 and 2 should be deemed part of the record on this motion and will be referred to in this brief using the same terminology as the brief supporting that motion. To the extent that additional documents are relevant, they are attached to the Steven M. Edwards Declaration in Support of Track 1 Defendants' Motion to Preclude the Expert Testimony of Dr. Raymond Hartman in Connection with Class 3 ("Supp. Edwards Decl.") submitted herewith. In addition, to the extent Plaintiffs intend to call Hartman as a witness at any trial to testify on any other topics – including those that were subjects of declarations filed in support of summary judgment – Hartman should be precluded from testifying on those subjects as well. *See, e.g., Poulis-Minott v. Smith*, 388 F.3d 354, 357-59 (1st Cir. 2004).

[2] *Id.* at 22-23.

[3] 6/26/06 Hearing Tr. 78.

[4] Hartman 12/15/05 Rpt. ¶ 22.

reasonably expected the spread to be on average . . . and compare this number to the actual spread . . . ." *In re Pharm. Indus. AWP Litig.*, 230 F.R.D. 61, 88 (D. Mass. 2005).

Hartman should only be permitted to offer this evidence if "the reasoning or methodology underlying the testimony is scientifically valid." *Daubert* 509 U.S. at 592-93. If his testimony is inconsistent with the evidence, or lacks an evidentiary basis, it should be excluded. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999). Plaintiffs should not be permitted to use Hartman to create evidence where none exists. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

We show below that there is no evidence to support Hartman's theory and, indeed, the evidence is overwhelmingly inconsistent with Hartman's views. Hartman's theory also makes no practical sense: he acknowledges that industry publications regularly apply a 25% mark-up factor to calculate AWP from a drug manufacturer's list price, WAC, and therefore Hartman is put in the untenable position of arguing that no manufacturer can discount more than 5% below list without either publishing a new list or committing fraud. We also show that there is no basis for Hartman's testimony that there is a causal link between allegedly inflated AWPs and injury to the class. Finally, we show that Hartman's damage calculations are wildly inaccurate and contrary to generally accepted economic theory.

Under the standards set forth in *Daubert*, therefore, his testimony should not be allowed.

Hartman's Theory[5]

Hartman concedes that the marketplace understood that AWP did not equal ASP. As he testified at his deposition:

[5] For a more detailed description of Hartman's theory, see the Class 1 and 2 Mem. at 2-6.

"Q: Well, why didn't you conclude that AWP should equal ASP?

"A. Because the industry knows that it doesn't."

(Hartman Dep. Tr. 669-70.)[6] According to Hartman, anyone who would suggest otherwise is "talking about a counterfactual world that runs against the way this industry has worked for the last 30 years." (*Id.* at 1279-80.)[7]

Hartman nevertheless maintains that TPPs "expected that AWP is larger than ASP by a reasonably predictable amount," and that amount did not exceed 30%. (Hartman 12/15/05 Rpt. ¶¶ 13, 59(a).)[8] He does not have any direct support for that theory. He has not conducted any surveys to determine TPP expectations (even though he said during the class certification phase that he would), and he cannot cite any depositions that support his theory. (Hartman Dep. Tr. 187-88, 705-06, 785-87.)[9]

Instead, Hartman relies on three surrogates to determine TPP expectations: (1) "comparator" drugs as to which there allegedly was no fraud; (2) public reports containing information concerning spreads; and (3) the "revealed preferences" of TPPs as evidenced by the terms of their contracts. (Hartman 12/15/05 Rpt. ¶¶ 22, 59.)[10] Hartman's comparator drugs are single source drugs that do not have competition, which he compares to drugs that face competition— an apples to oranges comparison. (*Id.* ¶ 22(a).) Hartman's public reports consist primarily of a study by the Office of Inspector General ("OIG") of the Department of Health and Human Services in December 1992, entitled "Physician's costs for Chemotherapy Drugs" (the "1992 OIG Report"), from which he purports to derive his 30% yardstick even though the report

[6] Edwards Decl. Exh. 7.
[7] Edwards Decl. Exh. 9.
[8] Edwards Decl. Exh. 2.
[9] Edwards Decl. Exh. 5, 7.
[10] Edwards Decl. Exh. 2.

depicts spreads in excess of 400%. (*Id.* ¶ 22(b).)[11] The TPP contracts that Hartman relies on are four contracts that are summarized in an attachment to his report, as well as a June 2003 report to Congress by the Medicare Payment Advisory Committee ("MedPAC"), entitled "Variation and Innovation In Medicare" (the "MedPAC Report"), which he claims reveal TPP expectations about spreads. (*Id.* ¶ 22(c) and Attach. C.)[12]

Once Hartman purports to establish his 30% yardstick, he determines liability and causation by comparing AWPs to ASPs. (Hartman 12/15/05 Rpt.¶ 56.)[13] According to Hartman, if AWPs exceed ASPs by more than 30%, there is liability and causation. (*Id.*) He engages in no other analysis of causation.

In his original report, Hartman calculated ASPs by using manufacturer data to determine the average prices to the customer classes that are covered under Medicare Part B, primarily physician and physician groups. (*Id.* ¶ 61.) Two months after the deadline for filing his original report, and without authorization from the Court, Hartman filed a supplemental report in which he changed his definition of ASP to encompass all customer classes, including hospitals, which had the effect of lowering ASPs and increasing the spreads. (Hartman 2/3/06 Rpt. ¶ 2.) [14] This increased the range of drugs for which Hartman can find liability and causation, but Hartman himself does not believe that the methodology used in his supplemental report is correct. At his deposition, Hartman testified that he stood by his original report and he created his supplemental report solely because plaintiff's counsel asked him to do so. (Hartman Dep. Tr. 647, 655-56, 1236-37, 1249, 1267.)[15]

[11] Edwards Decl. Exh. 21 at App. III. Hartman also purports to rely on a 2001 report by the American Society of Clinical Oncologists, but it does not contain any new information on spreads. Edwards Decl. Exh. 33.
[12] Edwards Decl. Exh. 36.
[13] Edwards Decl. Exh. 2.
[14] Edwards Decl. Exh. 3.
[15] Edwards Decl. Exhs. 7, 9.

Having determined liability and causation, Hartman then calculates damages by determining the dollar value of that portion of the spread that exceeds 30%. (Hartman 12/15/05 Rpt. ¶ 63-64.)[16] Using manufacturer data, he compares the ASPs to AWPs and then multiplies the excess over 30% by the number of units sold. Thus, if the AWP for NDC Y of drug X was $140 in 2000, and the ASP was $100, damages would be $10 times the number of units sold. (*Id.* ¶ 64.)

Argument

I. HARTMAN SHOULD NOT BE PERMITTED TO TESTIFY ABOUT HIS EXPECTATION THEORY IN A CLASS 3 TRIAL

Hartman's premise that TPPs "have expected that AWP is larger than ASP by a reasonably predictable amount" (Hartman 12/15/05 Rpt. ¶ 13) is demonstrably incorrect. The 1992 OIG Report, on which he relies, states quite clearly that "AWP is not a reliable indicator of the cost of a drug to physicians."[17] Furthermore, numerous TPPs have testified that they had no expectation that AWP exceeds ASP by a reasonably predictable amount. (Beaderstadt (John Deere) Dep. Tr. 72-73; Brown (BCBS/Miss.) Dep. Tr. 127; Cook (BCBS/MA) Dep. Tr. 202; Ellston (Ullico) Dep. Tr. 89-90; Gorman (BCBS/MA) Dep. Tr. 106; Killion (BCBS/MA) Dep. Tr. 136-38; Lemke (Humana) Dep. Tr. 123-24; Nieblyski (Health Alliance) Dep. Tr. 71-72; Plourde (BCBS/MA) Dep. Tr. 117; Spahn (Anthem) Dep. Tr. 98; Wert (Health Net) Dep. Tr. 35-37.)[18]

Joe Spahn, Senior Health Care Consultant for Anthem, testified that he had no such expectation:

[16] Edwards Decl. Exh. 2.
[17] Edward Decl. Exh. 21 at 2.
[18] Edwards Decl. Exhs. 37, 38, 44, 47, 48, 51; Supp. Edwards Decl. Exhs. 11, 13, 15, 19, 20, 22.

"Q. Prior to the break, we were talking about providers' acquisition costs and the fact they're not relevant to Anthem's reimbursement amounts. Do you recall that testimony?

"A. Yes.

"Q. Okay. And part of that was that Anthem has no information about what the providers' acquisition costs are, right?

"A. Correct.

"Q. So it's fair to say that Anthem has no particular expectation that providers' costs would be, you know, 10 percent, 30 percent, 50 percent, something more, something less than the amount they're reimbursed in relation to those drugs, right?

"A. Yes."[19]

Edward Lemke, Director of Fee Schedule Management for Humana made a similar point:

"Q. Is it Humana's expectation that the amounts that providers pay to acquire drugs are a fixed percentage less than the amount Humana reimburses in relation to those drugs?

"A. The expectation that – first of all, that it's fixed, no. The expectation that good business practice and assuming providers that we do business with practice good business practices, is that they would only accept payment that is at or above their costs. That's my only expectation.

"Q And certainly, you have no fixed expectation as to how much higher it would be than their acquisition costs, correct?

"A. Correct.

"Q. And indeed, that would vary from provider to provider, depending on what they paid to acquire drugs and what Humana reimburses them for drugs?

"A. Correct.

"Q. The percentage could be 10 percent in one case, 50 in another, 100 in another, correct?

"A. Could be."[20]

[19] Joe Spahn Dep. Tr. 97-98 (objections omitted). Edwards Decl. Exh. 51.
[20] Lemke Dep. Tr. 123-124 (objections omitted). Edwards Decl. Exh. 48.

Scott Wert, Vice President of Trade Relations for Health Net, was even more emphatic in stating that he had no expectation that AWP exceeded ASP by a reasonably predictable amount:

> "Q. So it's fair to say, isn't it, that the relationship between any individual entity's acquisition cost for drugs and the AWP for that drug will vary depending on the amount of rebates or discounts that that entity is getting, right?
>
> "A. Right.
>
> "Q. Indeed, there will be no settled percentage differential between the two of those numbers, the actual acquisition costs on the one hand and the AWP for that drug on the other, right?
>
> "A. Right.
>
> "Q. Will vary from entity to entity, drug to drug depending on the leverage that those entities have and their ability to exact differential rebates and discounts from drug manufacturers, right?
>
> "A. Yes.
>
> "Q. And certainly Health Net has no fixed expectation or has no expectation that there is, in fact, a fixed relationship between actual acquisition and AWP, correct?
>
> "A. Correct.
>
> "Q. In other words, Health Net recognizes that the relationship between the actual acquisition cost for a drug and the AWP for a drug will vary widely depending on the amounts of rebates or discounts that the purchasing entity can get from the manufacturer?
>
> "A. Right.
>
> "Q. So certainly, if one were to say that, well, you know Health Net expects that there will be a fixed relationship of, say, 20 percent or 30 percent or 40 percent, there would be absolutely no foundation for that, correct?
>
> "A. Correct.
>
> "Q. That would be simply an inaccurate assumption that lacks any foundation whatsoever, right?
>
> "A. Yes."[21]

[21] Wert Dep. Tr. 35-37 (objections omitted), annexed to Supp. Edwards Decl. as Exh. 22.

Hartman is unable to cite a single witness who supports his 30% yardstick. (Hartman Dep. Tr. 709-14, 785-87.) That is because no TPP had such an expectation. He picks his 30% expectation yardstick out of thin air.

There is substantial evidence that TPPs understood that there were spreads in excess of 30%. For example, Hartman maintains that TPPs acquired their understanding of spreads, in part, from government reports. (*Id.* at 956.) Those reports make it clear that there were spreads exceeding 400% in 1992 and 1000% in 1997. (*See* 1992 OIG Report at App. III; Report of the Committee on the Budget, House of Representatives, Balanced Budget Act of 1997 at § 10616 (June 24, 1997); OIG, *Excessive Medicare Payments for Prescription Drugs* at 8 (Dec. 1997); OIG, *Comparing Drug Reimbursement: Medicare and the Department of Veterans Affair* at ii (Nov. 1998); OIG, *Medicare Reimbursement of Prescription Drugs* at ii (Jan. 2001).)[22]

Moreover, the Barron's article, "Hooked On Drugs," published in June 1996, depicted spreads in excess of 700%.[23] In a speech in 1997, Lee Newcomer, the Chief Medical Officer of United Healthcare, a TPP class member, stated that "[t]he markups for chemotherapy medicines are getting to be so high that the public is beginning to react."[24] As a result, Hartman concedes that he cannot say that payors were not aware of megaspreads, and he acknowledges that at least some payors were aware. (Hartman Dep. Tr. 796, 798, 827-28.)[25]

In addition, four of the top five TPPs in Massachusetts, including class representative BCBS/MA,[26] purchased drugs directly from manufacturers.[27] As demonstrated by

[22] Edwards Decl. Exhs. 21, 25, 26, 28, 32. In addition, the Ven-A-Care letter, dated October 2, 1996, depicts spreads in excess of 1000%. Edwards Decl. Exh. 23 at 3.
[23] Edwards Decl. Exh. 22.
[24] Edwards Decl. Exh. 24 at 3.
[25] Hartman acknowledged that "Lee Newcomer understood the allegations in this matter and was making his voice heard . . . . " (Hartman Dep. Tr. 798.) Edwards Decl. Exh. 7.
[26] The others are Harvard Pilgrim Health Care, CIGNA HealthCare of Massachusetts and Fallon Community Health Plan.

defendants' expert Eric M. Gaier ("Gaier"), TPPs were able to acquire drugs from manufacturers at prices comparable to, and in some cases below, the ASPs calculated by Hartman.[28] Hartman acknowledges that TPPs acquiring drugs from manufacturers "would have more information" and consequently should be excluded from any damage analysis, but he made no effort to take that into account in his liability analysis. (Hartman Dep. Tr. 1013-19.)[29]

As noted above, since the direct evidence of actual expectations does not support his theory, Hartman relies on surrogates. His surrogates ("comparator" drugs, public reports, and "revealed preferences"), however, do not support his theory. To the contrary, individually and collectively, they refute his contention that TPPs based their reimbursement decisions on an expectation that AWPs did not exceed ASPs by more then 30%.

For comparator drugs, Hartman compares the spreads for drugs that face competition with drugs that do not and finds, not surprisingly, that competition causes discounting and consequently increases spreads. (Hartman 12/15/05 Rpt. ¶ 22(a); Hartman Dep. Tr. 969-70.)[30] It cannot be seriously disputed that TPPs are well aware of the effect of competition on spreads and therefore could not have based their expectations on the spreads of drugs that do not face competition. (Cannon (IHC Health Plans) Dep. Tr. 35-36; Herbold (Cigna) Dep. Tr. 85-86; Kenney (Harvard Pilgrim Health Care) Dep. Tr. 12-13, 15; Killion (BCBS/MA) Dep. Tr. 122, 126.)[31] Put another way, it defies basic economic science for Hartman to use payor expectations of spreads in the context of drugs enjoying patent monopolies to draw conclusions

---

[27] Declaration of Eric M. Gaier, Ph.D., in Support of Track 1 Defendants' Joint Motion for Summary Judgment dated March 15, 2006 ("Gaier 3/15/06 Decl.") ¶¶ 5-6, annexed to the Supp. Edwards Decl. as Exh. 7; Declaration of Eric M. Gaier, Ph.D., in Support of Track 1 Defendants' Joint Motion for Summary Judgment dated July 14, 2006 ("Gaier 7/14/06 Decl.") ¶¶ 8-9.
[28] Gaier 3/15/06 Decl. ¶¶ 7-8.
[29] Edwards Decl. Exh. 8.
[30] Edwards Decl. Exhs. 2 and 8.
[31] Edwards Decl. Exhs. 39, 45-47.

about their spread expectations in the multi-source/generic context. Hartman is comparing apples and oranges. (McFadden Rpt. ¶¶ 60-62, 83.)[32]

For publicly available information, Hartman primarily relies on the 1992 OIG Report. (Hartman Rpt. ¶ 22(b).)[33] That report depicts spreads exceeding 400%.[34] Taken together with other publicly available reports described above, they dramatically refute – rather than support – Hartman's 30% expectation yardstick. (McFadden Rpt. ¶¶ 64-67.)[35]

For his "revealed preference" theory, Hartman relies on four payor contracts and a MedPAC report depicting reimbursement rates ranging from AWP minus 15% to AWP plus 15% (a sample that cannot possibly be considered a reliable let alone a statistically significant representation of industry contracts). (Hartman Rpt. ¶ 22(c) and Attach. C.)[36] Even after having cherry-picked a tiny number of contracts, he is unable to explain how he derives his 30% yardstick from them. (Hartman Dep. Tr. 687-89, 700, 759.)[37] Nor is he able to reconcile his conclusion with TPP testimony that some contracts have reimbursement rates of AWP minus 45%. (*Id.* at 759.)[38]

More importantly, Hartman's revealed preference theory has it backwards. The revealed preference of TPPs is to use AWPs even though they know they may result in large spreads. (McFadden Rpt. ¶¶ 74-77.)[39] There are several reasons for this:

- Some TPPs use spreads to encourage physicians to establish clinics to treat patients outside of a hospital setting. (Coneys (BCBS/MA) Dep. Tr. 138-39; Goldman

[32] Edwards Decl. Exh. 11.
[33] Edwards Decl. Exh. 2 and 21.
[34] *See* Edwards Decl. Exh. 21 at App. III, which depicts invoice costs that are up to 83% below AWP. Converted to Hartman's methodology, which is to express spreads of a percentage above ASP, that translates into a number in excess of 400%.
[35] Edwards Decl. Exh. 11.
[36] Edwards Decl. Exh. 2.
[37] Edwards Decl. Exh. 7.
[38] *See* Herbold Dep. Tr. 21. Edwards Decl. Exh. 45.
[39] Edwards Decl. Exh. 11.

(Vista Health Plan) Dep. Tr. 58-59; Herbold (Cigna) Dep. Tr. 75-76; Mengert (Horizon) Dep. Tr. 78-81.)[40] The cost of treating a patient in an outpatient clinic is significantly less than treating that patient in the hospital. (Devaux (BCBS/MA) Dep. Tr. 176-77; Killion (BCBS/MA) Dep. Tr. 67; Plourde (BCBS/MA) Dep. Tr. 59-61.)[41] No doctor is going to undertake the cost and risk of setting up an outpatient clinic unless that physician can earn a reasonable return on the investment. (Haegele Rpt. ¶ 43-70; Morton Rpt. ¶ 138.)[42]

- Some TPPs use spreads to attract physicians to their networks. (Dragalin (MultiPlan) Dep. Tr. 15-16; Herbold (Cigna) Dep. Tr. 74-75; Killion (BCBS/MA) Dep. Tr. 119-20.)[43] Plaintiffs' other expert, Dr. Meredith Rosenthal, has acknowledged that TPPs compete for customers based on the extensiveness and quality of their networks and, as a consequence, physicians have market power. (Rosenthal Dep. Tr. 101-103, 249-252.)[44] If a TPP refuses to pay physicians enough to induce them to join its network, it will lose business. (Bell Rpt. ¶ 39.)[45]

- Some TPPs use spreads as a way of cross-subsidizing underpayment for services. (Beaderstadt (John Deere) Dep. Tr. 60; Herbold (Cigna) Dep. Tr. 28-29; Spahn (Anthem) Dep. Tr. 108-09.)[46] This is due, in part, to the fact that many TPPs use Medicare rates to reimburse physicians for services, and it is well-established that those rates are inadequate. (Bell Rpt. ¶¶ 41, 45; Gaier Rpt. ¶ 35-47; Morton Rpt. ¶ 75.)[47] Numerous

[40] Supp. Edwards Decl. Exhs. 10, 17; Edwards Decl. Exhs. 43, 45.
[41] Supp. Edwards Decl. Exhs. 12, 20; Edwards Decl. Exh. 47. *See also* GAO, *Medicare Reimbursement Policies Can Influence the Setting and Cost of Chemotherapy* at 4, 5 (July 1992). Edwards Decl. Exh. 20.
[42] Edwards Decl. Exhs. 14-15.
[43] Edwards Decl. Exhs. 40, 45, 47.
[44] Supp. Edwards Decl. Exhs. 3-4.
[45] Edwards Decl. Exh. 12.
[46] Edwards Decl. Exhs. 37, 45, 51.
[47] Edwards Decl. Exhs. 12-14.

TPPs have testified that they do not care about the cost of an individual drug; they just care about the bottom line. (Beaderstadt (John Deere) Dep. Tr. 76; Dragalin (MultiPlan) Dep. Tr. 15-16; Farias (Harvard Pilgrim Health Care) Dep. Tr. 152; Herbold (Cigna) Dep. Tr. 74-75; Lemke (Humana) Dep. Tr. 66-68; Spahn (Anthem) Dep. Tr. 59.)[48]

The experience of Blue Cross/Blue Shield of Massachusetts ("BCBS/MA"), the Class 3 representative, illustrates these factors at play. In 2004, in anticipation of ASPs becoming publicly available under the Medicare Modernization Act ("MMA"), BCBS/MA began to consider whether to abandon its AWP-based reimbursement approach. (Killion Dep. Tr. 87-89; Mulrey Dep. Tr. 71-73.)[49] Even though switching to an ASP-based system could theoretically enable it to save significant amounts of money on the drugs themselves, BCBS/MA decided not to change its reimbursement approach – or the amounts that it paid based on AWPs – because it was using profits on drugs to attract providers to its network and cross-subsidize low payments on services. (*Id.*)[50]

Trigon, another TPP and potential class member, has expressed a similar view that expressly recognized that spreads on older multi-source drugs are used to subsidize spreads on new drugs. In a letter to an oncology group it stated:

> "Trigon recognizes that your acquisition cost for drugs is slightly variable when expressed as a percent of the AWP. Ninety percent of AWP should provide you with substantial margins for some drugs and nearly zero margins for others. As you know, acquisition cost as a percent of AWP is much lower for the older and more established generics and multi-source brands. These relatively low-cost drugs provide substantial margins and are prominent in the established combination regimens for common malignancies. Therefore, on balance, providing drugs to Trigon

[48] Edwards Decl. Exhs. 37, 40, 42, 45, 48, 51.
[49] Edwards Decl. Exhs. 47 and 50.
[50] BCBS/MA also recently decided to use AWP or a reimbursement benchmark for hospitals. Cizauskas Dep. Tr. 124-26, annexed to Supp. Edwards Decl. as Exh. 9.

> insureds at ninety percent of AWP provides you with a positive margin, even when inventory costs are considered."[51]

Thus, Trigon's revealed preference was to arrive at a reimbursement formula that, "on balance," provided the physicians in its network with a "positive margin."

Hartman acknowledges the existence of these factors, but he did not consider them in his analysis. (Hartman Dep. Tr. 979-80, 1055, 1061-66, 1205-06.)[52] He did not conduct surveys of payor expectations; he did not consider whether TPPs compete for physicians; he did not investigate how TPPs negotiate with physicians; he did not analyze provider market power; he did not consider the impact of competition; and he was instructed by counsel to ignore cross-subsidization. (*Id.* at 705-06, 854-55, 857-59, 864, 1031-32, 1035-36, 1039, 1055, 1057, 1063, 1065.) In short, he has not done any of the things that an economist would normally do in arriving at an opinion on market expectations. (McFadden Rpt. ¶ 10.)[53]

One of defendants' experts, Dr. Daniel L. McFadden, a Nobel prize winning economist whose prize-winning work focuses on the area of econometrics that Hartman tries unsuccessfully to employ, concluded that Hartman's theory is "unreliable and incorrect;" his "assumptions and conclusions contradict basic economic theory and are inconsistent with the evidence he presents;" and his approach is "not scientific." (McFadden Rpt. ¶ 10.) Dr. Gregory K. Bell, an economist who specializes in the pharmaceutical industry, concluded that Hartman's expectation theory "is inconsistent with the economics of the pharmaceutical industry." (Bell Rpt. ¶ 21.)[54] Gaier characterized Hartman's theory as "unscientific and unreliable" as well as "inappropriate" and "arbitrary." (Gaier Rpt. ¶¶ 9-11.)[55] Dr. Fiona M. Scott Morton, an

[51] Supp. Edwards Decl. Exh. 5.
[52] Edwards Decl. Exhs. 7-9.
[53] Edwards Decl. Exh. 11.
[54] Edwards Decl. Exh. 12.
[55] Edwards Decl. Exh. 13.

economist who teaches at Yale, stated that "Dr. Hartman's 'yardstick' is clearly arbitrary, scientifically unreliable, and deceptive." (Morton Rpt. ¶ 21.)[56]

At bottom, Hartman is forced to concede that he is not in a position to say that any particular payer has been deceived. (Hartman Dep. Tr. 813, 846, 937, 940.)[57] Nor is he able to explain why his expectation yardstick, or "speed limit," should be set at 30%, as opposed to 40% or 50% or variable percentages. (*Id.* at 785-87, 981-84.) He admits that his yardstick is something "I have been asked to assume." (*Id*. at 842.)

This case is remarkable for the fact that testimony of TPPs consistently refutes the central thesis of the Plaintiffs' case. Plaintiffs are using Hartman to shore up that thesis – that spreads exceeded expectations – precisely because the evidence refutes it. That is not a proper use of an expert. "[A]n expert should not be permitted to give an opinion that is based on conjecture or speculation from an insufficient evidentiary foundation." *Damon v. Sun Co.*, 87 F.3d 1467, 1474 (1st Cir. 1996) (citation omitted). "[A]n expert must vouchsafe the reliability of the data on which he relies and explain how the cumulation of that data was consistent with standards of the expert's profession." *SMS Sys. Maint. Servs., Inc. v. Digital Equip. Corp.*, 188 F.3d 11, 25 (1st Cir. 1999). Where, as here, an expert opinion is inconsistent with the evidence it should be excluded. *See, e.g., Ed Peters Jewelry Co. v. C & J Jewelry Co.*, 124 F.3d 252, 259-60 (1st Cir. 1997) (expert testimony that was "internally inconsistent and unreliable" excluded).

[56] Edwards Decl. Exh. 14.
[57] Edwards Decl. Exhs. 7-8.

II. HARTMAN SHOULD NOT BE PERMITTED TO TESTIFY AS TO CAUSATION

Hartman assumes that if he can show that AWPs exceeded expectations, causation automatically follows. (Hartman 12/15/05 Rpt. ¶ 56.)[58] That is not correct. Hartman's report is devoid of any analysis that would support a causal connection.

A number of payers have testified that prices would not be any different in the "but for" world – i.e. a world in which all payers understood the difference between AWP and acquisition cost. (Farias (Harvard Pilgrim Health Care) Dep. Tr. 152-53; Maxwell (University of Pittsburgh Medical Center Health Plan) Dep. Tr. 156; Sidwell (John Deere) Dep. Tr. 68-69; Spahn (Anthem) Dep. Tr. 93-95.)[59] Hartman had no explanation for this testimony at his deposition – other than to reject it out of hand. (Hartman Dep. Tr. 1061-62.)[60] There are a number of reasons why reimbursement in the but for world would not change, some of which Hartman acknowledges.

First, as Hartman admits, reimbursement is governed by a number of factors other than AWP. As noted above, the amount of money that a TPP pays a physician for drugs is a product of the TPP's desire to influence site of care; the TPP's need to create a network; the interdependencies between drugs and services; and the physician's market power. (Hartman Dep. Tr. 870-73.) Those factors would still exist in the but for world, but Hartman has not taken them into account. (*Id.* at 979-80, 205-06.)[61]

Second, reimbursement amounts are the product of competition. A number of payers have testified that they simply bargain with providers until they arrive at a rate that is acceptable to both sides in the negotiation. (Beaderstadt (John Deere) Dep. Tr. 75-76; Eddy

[58] Edwards Decl. Exh. 2.
[59] Edwards Decl. Exhs. 42 and 51; Supp. Edwards Decl. Exhs. 16 and 21.
[60] Edwards Decl. Exh. 8.
[61] Edwards Decl. Exhs. 8-9.

(Empire) Dep. Tr. 74-76; Morris (Anthem) Dep. Tr. 68-69.)[62] Hartman did not take that into account. (Hartman Dep. Tr. 1029.)

Defendants' expert, Gaier, analyzes this issue in some detail. (Gaier Rpt. ¶¶ 75-88.)[63] He concludes that "TPPs in Massachusetts and elsewhere are able to exert leverage over providers to achieve competitive reimbursements that balance their desire to minimize costs with their need to maintain network access for their beneficiaries." (*Id*. ¶ 88.) Similarly, McFadden points out that competition among sellers can enable the purchaser of a product or service to obtain the lowest price even if the purchaser does not know the seller's cost. (McFadden Rpt. ¶¶ 15-17.)[64]

Third, ASPs are now available to TPPs as a result of the MMA but in many cases reimbursement amounts have not changed. BCBS/MA is a prime example of this: it considered changing its reimbursement approach to an ASP-based system but decided not to. One BCBS/MA witness testified that the industry standard for reimbursement remains 95% of AWP. (Killion Dep. Tr. 89.)[65] There is no basis for Hartman to reach a conclusion that is contrary to what actually happened. An economist can interpret the facts; but he cannot make them up. *Kumho Tire*, 526 U.S. at 157.

Furthermore, for multi-source drugs, both the government and private payers used the median AWP for all sources of the generic form of the drugs as well as MACs, and other reimbursement formulae not tied to the AWP of any particular product. (42 C.F.R. §405.17 (1998); Brown (BCBS/Miss.) Dep. Tr. 39-42; Miller (Anthem) Dep. Tr. 86-88.)[66] Hartman has done no analysis to tie the AWP of any manufacturer to the reimbursement amount. (Hartman

[62] Edwards Decl. Exhs. 37, 41, 49.
[63] Edwards Decl. Exh. 13.
[64] Edwards Decl. Exh. 11.
[65] Edwards Decl. Exh. 47.
[66] Edwards Decl. Exhs. 27, 38; Supp. Edwards Decl. Exh. 18. This analysis applies to Classes 1 and 2 as well.

Dep. Tr. 1373-74.)[67] Under the circumstances, he cannot establish any causal link between the alleged deception and damages.[68]

In several unauthorized declarations in connection with the summary judgment briefing, Hartman tried to eliminate this problem abandoning his competition-based "leap-frog" argument and asserting that manufacturers of a multi-source drug collude to inflate the median AWP for that drug, saying that the motive for such collusion is to enable manufacturers to compete against therapeutic alternatives to their multi-source drug. (*See* Declaration of Raymond S. Hartman in Opposition to Defendants' Motions for Summary Judgment dated April 6, 2006 ¶¶ 19-21, 30; Reply Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Summary Judgment ("Hartman 4/27/06 Reply Decl.") dated April 27, 2006 ¶¶ 33-47.)[69] This theory was not in his report and defendants have not had an opportunity to depose him on it. (Supp. Edwards Decl. ¶ 2.) More importantly, there is no analysis to support it; nor can there be, since there is no record to support this entire construct.

Throughout this litigation, plaintiffs have alleged that defendants *competed*, not that they *colluded*, on the basis of AWPs. They have not, and cannot, identify a single potential alternative therapeutic competitor to support their claim of collusion. Moreover, for multi-sources drugs dispensed by pharmacies, Hartman's construct is a legal and functional

[67] Edwards Decl. Exh. 9.

[68] This flaw in Hartman's theory is particularly significant for a brand manufacturer such as BMS. All of BMS's drugs except two are brands that lost their patent protection and became multi-source. Merits Report and Declaration of Gregory K. Bell dated March 15, 2006 ("Bell BMS Rpt.") ¶¶ 12-19, annexed without exhibits to the Supp. Edwards Decl. as Exh. 6. As a general matter, once BMS's brands became multi-source, BMS did not implement any further changes in their list prices. (Bell BMS Rpt. ¶ 27.) Furthermore, BMS only reported initial prices and price changes to the publications, there were no further communications and BMS's list price (and hence the AWP) remained the same. Declaration of Denise Kaszuba dated July 13, 2006 ¶¶ 3-4. Since the AWPs for BMS's multi-source drugs were at the brand level, and the median price resulting from generic competition would – by definition – be below the brand, there could not be any causal connection between the AWP for the BMS drug and the reimbursement amount.

[69] Supp. Edwards Decl. Exhs. 1 and 2.

impossibility, since pharmacies cannot dispense a "therapeutic alternative" to a prescribed drug. There cannot be collusion, tacit or otherwise, to bring about what is impossible.

Furthermore, for tacit collusion to occur, three conditions must exist: (1) it must be in the best interest for parties to collude; (2) it must be possible to detect deviations from the agreement; and (3) there must be a mechanism for punishing such deviations. (Addanki Decl. ¶¶ 28-31.)[70] None of these conditions exists here. Manufacturers have no incentive to agree on AWPs or discounts – especially if they supposedly use spreads to compete; there is no way to detect deviations from an agreed upon spread because discounts are confidential; and it is difficult to conceive of any punishment mechanism in an environment in which there is fierce competition among generic drugs. (*Id.*)

But Hartman has not one scintilla of evidence to support this dubious theory of collusion and, for that reason alone, he should be prevented from testifying about it. An expert's testimony on causation is not admissible if it is simply based on assumptions. *American Booksellers Ass'n., Inc. v. Barnes & Noble, Inc.*, 135 F. Supp. 2d 1031, 1041 (N.D. Cal. 2001). The whole point of the expert's testimony is to establish a causal link so the fact-finder has more to go on than mere assumptions. *Country Road Music, Inc. v. MP3.com, Inc.*, 279 F. Supp. 2d 325, 330-31 (S.D.N.Y. 2003); *Polaino v. Bayer Corp.*, 122 F. Supp. 2d 63, 69-70 (D. Mass. 2000). An expert's testimony must be based on something more than "the *ipse dixit* of the expert." *Joiner*, 522 U.S. at 146.

III. HARTMAN'S DAMAGE CALCULATIONS ARE UNRELIABLE

All of the arguments set forth above that relate to causation also affect damages. If the Court concludes that Hartman has not established that prices would be different in the but

[70] Supplemental Declaration of Sumanth Addanki dated April 27, 2006 ("Addanki Decl.") ¶ 21, annexed to Supp. Edwards Decl. as Exh. 8.

for world, or he has not demonstrated a causal connection between allegedly deceptive AWPs and injury to the class, there is no injury and therefore no damage. If the court concludes that these factors may have had an impact on damages, but did not eliminate them altogether, then they clearly affect the amount of damages. Hartman has done nothing to take that into account. (Hartman Dep. Tr. 1099-01.)[71]

Moreover, all of the flaws in Hartman's damage calculation pointed out in the Class 1 and 2 *Daubert* motion exist for Class 3. Hartman has not considered the impact of reimbursement for drugs on the level of reimbursement for services; he has not considered whether prices would go up in a world in which spreads were limited to 30% (because 30% of a higher number would generate high profits for physicians); he has not considered whether co-payments are actually collected; and he makes assumptions concerning missing data that skew the results in favor of plaintiffs. (Class 1 and 2 Mem. at 25-30.)

In addition, Hartman assumes – incorrectly – that all TPP contracts are based on AWP. This comes about as a result of his use of manufacturer data to calculate damages. Hartman determines damages by calculating the extent to which the discounts that defendants gave to providers exceeded 30% of AWP. (Hartman 12/15/05 Rpt. ¶ 65.)[72] In many cases, however, the contracts by which providers obtained those discounts were not based on AWP. (Gaier Rpt. ¶¶ 115-26.)[73] They were based on other criteria such as usual and customary charges, or they were capitated contracts. (Fox (BCBS/MA) Dep. Tr. 314-15; Mulrey (BCBS/MA) Dep.

[71] Edwards Decl. Exh. 8.
[72] Edwards Decl. Exh. 2. In other words, Hartman's theory is that defendants should have to pay twice: once for the discount they gave to the provider and a second time as damages to plaintiffs in the amount of that discount.
[73] Edwards Decl. Exh. 13.

Tr. 36-37, 40, 43, 49, 57.)[74] Since Hartman relies on manufacturer data only, he has no way of identifying which sales were based on benchmarks other than AWP. (Hartman Dep. Tr. 1083.)[75]

There is also a fundamental inconsistency in Hartman's approach. He excludes sales to entities that acquire drugs because, as beneficiaries of spreads, they have knowledge of spreads. (Hartman Dep. Tr. 1013-14.) Thus, if a TPP such as BCBS/MA owned an HMO, Hartman excludes sales to that HMO in his damage analysis. (Hartman 12/15/05 Rpt. ¶ 63.) Nevertheless, he *includes* reimbursements by that same TPP in his damage analysis even though he acknowledges that a TPP "whose subsidiaries buy drugs directly hopefully should be informed by those subsidiaries" of the prices of the drugs. (Hartman Dep. Tr. 1015.) The damage claim of any TPP who acquired drugs directly should be excluded in its entirety.

Hartman's approach also produces anomalous results. By aggregating data on an annual basis, Hartman produces results where a manufacturer with two transactions – one of which had a spread of zero and the other of which had a spread of 60% – would not be liable; but another manufacturer with two transactions – one of which had a spread of 28% and the other of which had a spread of 33% – would pay damages on both. (*See* McFadden Rpt. ¶¶ 128-31.)[76] Hartman had no answer for this other than to say that he was not giving "speeding tickets" on a transaction-by-transaction basis. (Hartman Dep. Tr. 1094-95.)

Hartman's calculation of ASPs in his supplemental report should be excluded as well. He admitted that he only created the supplemental report at the request of counsel, and his original report is his only "economic analysis." (Hartman Dep. Tr. 647, 656, 664-65, 1245.)[77] The central thesis of Hartman's theory is that TPPs expected that the ASPs of the providers they

[74] Supp. Edwards Decl. Exh. 14; Edwards Decl. Exh. 50.
[75] Edwards Decl. Exh. 8.
[76] Edwards Decl. Exh. 11.
[77] Edwards Decl. Exhs. 7 and 9.

were reimbursing, such as physicians, were within 30% of the AWPs that the TPPs were using as a reimbursement benchmark. To redefine ASPs to include other providers, such as hospitals, completely distorts the analysis because it is well-known that hospitals pay considerably less than physicians for drugs. (Hartman Dep. Tr. 656.) Hartman should not be permitted to replace his "economic analysis" with a theory concocted by plaintiffs' counsel for purposes of litigation. *See Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) (on remand).

Finally, as explained in Schering's and Warrick's Opposition to Plaintiffs' Motion for Partial Summary Judgment, plaintiffs conflate provider's cost with manufacturer's price and do not account for the markups of wholesalers or other intermediaries, thus failing to proffer evidence of an essential element of their claims, namely, that AWPs were inflated in relation to provider cost. (Schering's and Warrick's Opp'n to Pls.' Mot. for Summ. J. at 2-4.) Despite arguing for years that defendants' AWPs should have been more closely related than they were to the actual costs paid by the physicians and pharmacies that administer or dispense the drugs, plaintiffs admit that they have no record evidence of providers' costs. (*Id.*) Plaintiffs attempted to fill this critical gap in the record by submitting yet another declaration from Hartman in support of their reply papers on summary judgment as to Class 2. Without citation to any evidence source whatsoever, Hartman baldly asserted that wholesaler markups "are known to be paper thin and *de minimis* for the purposes here." (Hartman 4/27/06 Reply Decl. ¶ 39).[78] Hartman's say-so, however, is not a legally sufficient substitute for evidence of facts subject to definite ascertainment. *See Joiner*, 522 U.S. at 146. Thus, without any evidence to support him, Hartman should not be permitted to testify about this subject.

With respect to Warrick's albuterol, Hartman's analysis is seriously flawed. In order to determine what percentage of Warrick's albuterol sales to which to attribute

[78] Supp. Edwards Decl. Exh. 2.

reimbursement by Medicare, he simply guesses that it is 75%. (Hartman 12/15/05 Rpt. Attach. J.7.a).[79] He then allots the remaining 25% of albuterol sales to "non-Medicare" or private reimbursement and 0% for reimbursement by Medicaid. (Hartman Decl., attachment J.7.a). In total, he purports to account for 100% of all Warrick albuterol sales. At his deposition, however, he conceded that his methodology and conclusions are inconsistent with the expert disclosure he submitted in the AWP suit against Warrick and others filed by the State of Connecticut. (Hartman Dep. Tr. 1392-1401). In that case, in which Connecticut – also represented by Hagens Berman Sobol Shapiro LLP – alleges Medicaid-based claims that are analogous to those presented here, Hartman attributed 25% of Warrick's albuterol sales to Medicaid reimbursement. (*Id.*) Thus, between the two cases, Hartman has calculated damages based on 125% of Warrick's albuterol sales, a mathematical impossibility.[80] Hartman cannot be permitted to testify based on entirely unsubstantiated assumptions that are, themselves, inconsistent with one another.

[79] Edwards Decl. Exh. 2.

[80] Although they are even less lucid than Hartman's declaration in the private class action, the recently filed declarations by Hartman in the actions brought by the states of Nevada and Montana before this Court purport to find even more damages with respect to Warrick's albuterol, inflating his farcical numbers even higher.

Conclusion

For the foregoing reasons, Hartman should not be permitted to testify in any trial of Class 3 claims.

Dated: Boston, Massachusetts
July 14, 2006

Respectfully Submitted,

By: /s/ Jacob T. Elberg (BBO No. 657469)

Thomas E. Dwyer (BBO No. 139660)
Jacob T. Elberg (BBO No. 657469)
DWYER & COLLORA, LLP
600 Atlantic Avenue
Boston, MA 02210
Tel: (617) 371-1000
Fax: (617) 371-1037
tdwyer@dwyercollora.com
jelberg@dwyercollora.com

Steven M. Edwards (SE 2773)
Lyndon M. Tretter ((LT 4031)
Admitted *pro hac vice*
HOGAN & HARTSON LLP
875 Third Avenue
New York, NY 10022
Tel: (212) 918- 3000
Attorneys for Defendant Bristol-Myers Squibb Company

CERTIFICATE OF SERVICE

I, Lyndon Tretter, certify that a true and correct copy of the foregoing document was served on all counsel of record by e-mail and electronic service pursuant to Paragraph 11 of the Case Management Order No. 2 on July 14, 2006 by sending a copy to Lexis/Nexis for posting and notification to all parties.

_____/s/ Lyndon Tretter_____
Lyndon Tretter